

020449\_5029.PDF

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

**APPLICATION NUMBER:**

**20-449/s-029**

***Trade Name:*** Taxotere

***Generic Name:*** Docetaxel

***Sponsor:*** Aventis Pharmaceuticals, Inc.

***Approval Date:*** August 18, 2004

***Indications:*** Provides for the use of Taxotere (docetaxel) in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer.

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**20-449/s-029**

## CONTENTS

### **Reviews / Information Included in this NDA Review.**

<b>Approval Letter</b>	<b>X</b>
<b>Approvable Letter(s)</b>	
<b>Final Printed Labeling</b>	<b>X</b>
<b>Medical Review(s)</b>	<b>X</b>
<b>Chemistry Review(s)</b>	<b>X</b>
<b>EA/FONSI</b>	
<b>Pharmacology Review(s)</b>	
<b>Statistical Review(s)</b>	<b>X</b>
<b>Microbiology Review(s)</b>	
<b>Clinical Pharmacology/ Biopharmaceutics Review(s)</b>	<b>X</b>
<b>Administrative Document(s) and Correspondence</b>	<b>X</b>

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-449/s-029**

**APPROVAL LETTER(S)**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-449/S-029

Aventis Pharmaceuticals, Inc.  
200 Crossing Boulevard  
P.O. Box 6890  
Bridgewater, NJ 08807-0890

Attention: Cheryl Anderson  
Senior Director, Global Regulatory Liaison

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated March 17, 2004, received March 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxotere® (docetaxel) for Injection Concentrate, 20 mg and 80 mg.

We acknowledge receipt of your submissions dated May 26, June 3, 4, August 3, 4, 5 and 18, 2004.

This supplemental new drug application provides for the use of Taxotere® (docetaxel) in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-449/S-029." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submission dated August 18, 2004. This commitment is listed below.

**Description of Commitment:**

To submit a complete report of the updated TAX316 data to verify the efficacy based on 700 events of DFS and safety of Taxotere in the adjuvant treatment of women with operable node-positive breast cancer and to submit the final analysis of overall survival (expected to occur in the year 2010).

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).